Application No.: 10/765,067

Art Unit: 1644

#### **REMARKS**

Claims 1-14 are pending in the present application. Claims 4-6 are withdrawn from consideration. Claims 1-3 and 7-14 stand rejected. Claims 1, 9 and 12 are amended herein. Claims 2, 3, 11, 13-14 are cancelled herein without prejudice or disclaimer. Support for amended claims 1, 9 and 12 and can be found, for example, at page 10, second paragraph and in Example 5, page 24 of the specification. No new matter is added.

## 35 U.S.C. § 112, first paragraph

Claims 1-3 and 7-14 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly containing a recitation that was not clearly presented in the specification. Specifically, the Examiner alleges that the terms "suspension culture" and "spinning culture" are not clearly described in the specification. The Applicants respectfully disagree with the Examiner's allegation. However, in an effort to advance prosecution, the Applicants remove this term from claims 1, 9 and 12 herein. Claims 2, 3, 11, 13, and 14 are cancelled herein without prejudice or disclaimer, thus, rendering rejection of these claims moot.

Applicants respectfully submit that, in view of the forgoing remarks, the Applicants have overcome the rejection of claims 1, 7-10 and 12 under 35 U.S.C. § 112, first paragraph. Accordingly, the Applicants respectfully request withdrawal of these rejections.

### 35 U.S.C. § 103(a)

Claims 1-3 and 7-14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Adair, et al. in view of Queen, et al., U.S. Patent No. 5,530,101 or Waldman et al., U.S. Patent No. 5,846,534. Specifically, the Examiner alleges that Adair, et al. teach methods of providing glycosylated antibodies and also the advantages of modifying the glycosylation of such antibodies as it applies to activating complement. The Examiner concedes that Adair, et al. differs from the instant claims in that Adair, et al. does not disclose the elected invention of treating arthritis. The Examiner goes on to allege that Queen, et al., teach methods for reducing immunogenicity to antibodies and also single and multiple administration depending on the severity of the disease. Finally, the Examiner refers to Waldman, et al. as teaching recombinant antibodies to treat autoimmune disease.

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The Applicants respectfully traverse this rejection. To establish a *prima facie* case of obviousness, the Examiner must show that the cited references teach or suggest all the features recited in the claim. Assuming *arguendo*, that even if the combination of references teaches each feature, the Examiner must provide some articulated reasoning with some rational underpinning regarding why a person having ordinary skill in the art would combine the cited references to obtain the subject matter claimed by the Applicant. *See KSR v. Teleflex, Inc.*, 127 S.Ct. 1727, 1731 (2007). The Examiner must also show that in view of the cited art at the time of Applicants' invention, a person having ordinary skill in the art would have had a reasonable expectation of successfully arriving at the claimed subject matter. *See id.* at 1740; *see also* M.P.E.P. § 2143.02 (*citing In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986)).

In his rejection of claims 1-3 and 7-14 the Examiner concedes that Adair, et al. do not teach the treatment of arthritis with glycosylated antibodies. The Examiner also alleges that Waldman, et al. teach that recombinant antibodies including CAMPATH-1 can be used to treat "autoimmune diseases including rheumatoid arthritis." The Applicants respectfully disagree. Waldman, et al. do disclose at column 4 lines 30-33, that "Such reshaped antibodies have been used in the treatment of patients with non-Hodgkin lymphoma, as well as in the treatment of some cases of autoimmune disease." However, they do not indicate that glycosylated antibodies can be used for the treatment of rheumatoid arthritis. The Applicants respectfully submit that none of the references cited by the Examiner teach or suggest methods of treating a patient with rheumatoid arthritis with a human or humanized antibody glycosylated in a CHO cell. Furthermore, the Examiner has not shown that a person of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed subject matter. Thus, the examiner has not met his burden of establishing prima facie obviousness.

Applicants respectfully submit that, in view of the forgoing remarks, the Applicants have overcome the rejection of claims 1, 7-10 and 12 under 35 U.S.C. § 103. Claims 2, 3, 11, 13-14 are cancelled herein without prejudice or disclaimer, thus, rendering rejection of these claims moot. Accordingly, the Applicants respectfully request withdrawal of these rejections.

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# Obvious-type double-patenting

Claims 1, 2 and 7-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 12, 17, 21-28, 39 and 40 of co-pending application USSN 10/145,992 in view of Mather, et al. (U.S. Pat. No. 5,122,469), Zettlemeissl, et al. (Biotechnology 5:720-725(1987)), Handa-Corrigan, et al. (Enzyme Microb. Technol. 11:230-235 (1989)) and Schneider (J. Immunol. Methods 116:65-77 (1989)). The Applicants amend claims 1 and 9 herein to recite rheumatoid arthritis, thus, rendering obvious type double patenting over co-pending application USSN 10/145,992 moot. The Examiner notes that given the species of arthritis in the instant application and the election of non-Hodgkin's lymphoma in the co-pending application, claims drawn to species disease of the instant application are not included in this provisional double patenting rejection. However, should it be determined that a terminal disclaimer is necessary after allowable subject matter has been agreed, Applicants will timely file such disclaimer.

## Conclusion

The Applicants reserve the right to prosecute, in one or more patent applications, the claims to non-elected inventions, the cancelled claims, the claims as originally filed, and any other claims supported by the specification. The Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration and allowance of the pending claims is earnestly solicited. If it would expedite the prosecution of this application, the Examiner is invited to confer with the Applicants' undersigned attorney.

Respectfully submitted.

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